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10/599,855

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EXAMINER

MERENE, JAN CHRISTOP L

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,855	Applicant(s) THAKKAR, NAVIN N.	
	Examiner JAN CHRISTOPHER MERENE	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/26/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This is the initial Office action based on the 10/599,855 application filed on October 11, 2006, which is a 371 of PCT/IN05/00102 filed on April 7, 2005. Claim 1-26, as originally filed, are currently pending and have been considered below. Claim 1 is independent.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claims 1-26** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regards to **Claim 1**, the applicant recites:

In line 6, "...proximal holes directed..."

In line 10, "... and at the same time..."

In line 14, "...are making..."

In line 21, "...is having plurality..."

In lines 29-30, "... is having anterior curvature..."

In lines 37-38, "...with mores taper towards leading end..."

In line 42, "...part is having at least..."

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This is just a small sample of the indefinite and confusing language of the applicant. The examiner respectfully requests the applicant to carefully review the claims. The examiner will treat the claims with art as best understood in view of the 112 rejections.

4. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

5. **Claim 23** is further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 recite recites the limitation "end cap" in lines 1-2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Objections

6. **Claims 20-21** are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A multiple dependent claim is a dependent claim which refers back in the alternative only. See MPEP 608.01(n)

Specification

7. A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. **Claims 1-23, 25-26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zirkle, JR US 2002/0151897 in view of Crickenberger et al US 5,728,128, Brumfield US 5,562,666, Vesbty US 3,892,233, Weaver US 6,623,486, and Luter US 5,951,557.

Zirkle, JR discloses an implant assembly for treating proximal femur fractures and same side fractures of shaft of femur comprising;

a compact targeting device (see Fig 1 and 4 below) having connecting end (#56) to connect with thigh end (#14) of intramedullary nail (#12) by temporary connecting bolt (#50), a handle part (#56), block of plural proximal holes (#26) and block of plural distal holes (#30).

However Zirkle, JR does not explicitly disclose the axis of said proximal holes directed towards head and neck of femur is making an angle of 120° to 140° with longitudinal axis of medullary canal of femur to match the neck shaft angle of femur to target corresponding proximal holes of intramedullary nail and at the same time the plane of said proximal holes is making an angle of 5° to 20° with horizontal plane passing through long axis of femur, intramedullary nail and said plural distal holes to match the ante version angle of head and neck of femur and axis of said distal locking holes are making an angle of 90° with longitudinal axis of intramedullary nail when said intramedullary nail is in position in medullary canal of femur.

It would have been obvious to one having ordinary skill in the art to construct the device with the axis of said proximal holes directed towards head and neck of femur is making an angle of 120° to 140° with longitudinal axis of medullary canal of femur to match the neck shaft angle of femur to target corresponding proximal holes of intramedullary nail and at the same time the plane of said proximal holes is making an angle of 5° to 20° with horizontal plane passing through long axis of femur, intramedullary nail and said plural distal holes to match the ante version angle of head and neck of femur and axis of said distal locking holes are making an angle of 90° with

longitudinal axis of intramedullary nail when said intramedullary nail is in position in medullary canal of femur to accommodate the different sizes of patients

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device with the axis of said proximal holes directed towards head and neck of femur is making an angle of 120° to 140° with longitudinal axis of medullary canal of femur to match the neck shaft angle of femur to target corresponding proximal holes of intramedullary nail and at the same time the plane of said proximal holes is making an angle of 5° to 20° with horizontal plane passing through long axis of femur, intramedullary nail and said plural distal holes to match the ante version angle of head and neck of femur and axis of said distal locking holes are making an angle of 90° with longitudinal axis of intramedullary nail when said intramedullary nail is in position in medullary canal of femur, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Zirkle, JR does not specifically disclose an intramedullary nail of short length and full length version and a cannulated connecting bolt (as applied to Claim 3 and 23, where #50 can act as both a connecting bolt as well as an end cap, where #50 is threaded and fits into the head end of intramedullary nail #12, see paragraph 34) and intramedullary nail is cannulated (as recited claim 24).

However, Crickenberger et al discloses a similar device with a cannulated connecting bolt (#77), a targeting device (#41) and a cannulated intramedullary nail

(#13). It would have been obvious to one having ordinary skill in the art to modify the connecting bolt/end cap (#50) and intramedullary nail (#12) of Zirkle, JR to be cannulated because it provides internal access to an intramedullary nail for placement of an element such as a wire (see abstract and see Col 4 lines 48-51, where #77 has aperture #83 and Fig 3). It would have also been obvious to one having ordinary skill in the art to provide an intramedullary nail of short length and full length version to accommodate patients's of different sizes. Crickenberger et al discloses the device may include a plurality of assembled targeting devices/stems of different sizes, neck angles, etc. (see Col 5 lines 16-20).

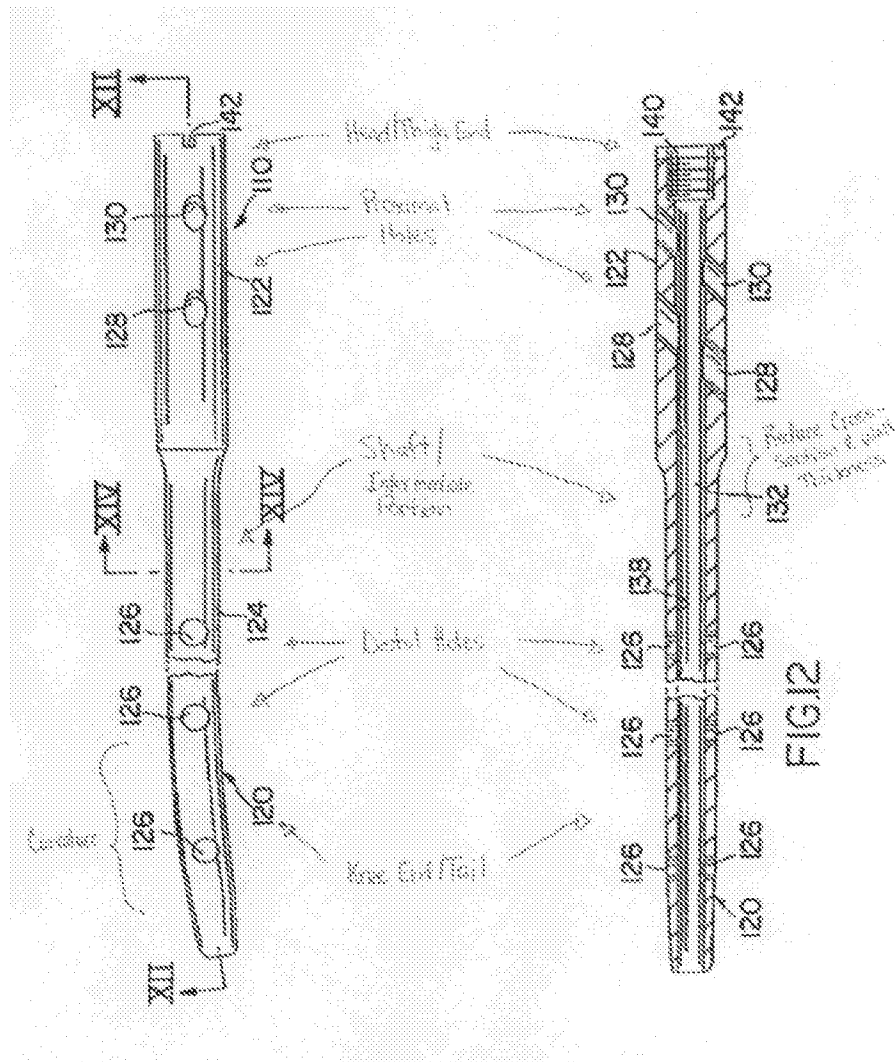
Brumfield discloses the use of two nails of different sizes (#110 and #10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the short (#110) and long (#10) nails of Brumfield et al to the assembly of Zirkle, JR and Crickenberger because it provides two nails of different sizes (as seen in Figs 1-1A)

Brumfield discloses a unitary intramedullary nail of short length version (#110 as seen in Figs 1A, 11-12) and full length version (#10 as seen in Figs 1-2) being adapted in use for insertion into the medullary canal of a femur, is cannulated in whole length (as seen in figs 3-4 for #10 and Fig. 12 for #110), having thigh end portion or head, intermediate portion or shaft and knee end portion or tail , where said shaft is having plural distal holes to hold distal fragment of femur in said short length version and said knee end is having anterior curvature, and plural distal holes in said full length version and axis of said distal holes is making an angle of 90° with longitudinal axis of medullary

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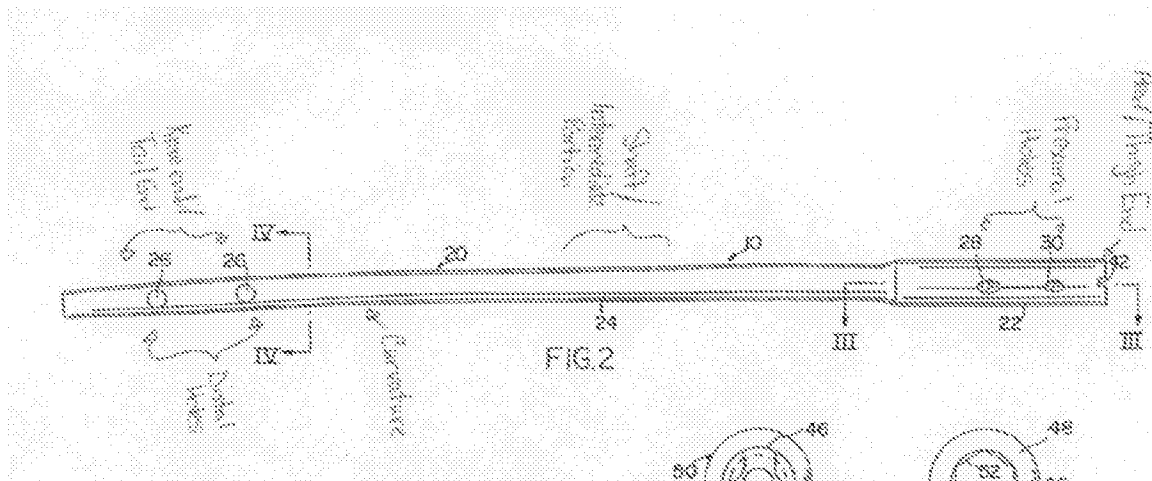
canal and said intramedullary nail when said intramedullary nail is in position in medullary canal (as seen in Fig 1, where #10 has proximal holes oriented at 90 degrees with respect to the femur and see Figs below);

Short Version:



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Long Version:



Brumfield discloses the proximal holes at an angle as seen above but does not specifically disclose the proximal holes directed towards head and neck of femur is making an angle of 120° to 140° with longitudinal axis of medullary canal and said nail to match neck shaft angle of femur and at the same time the plane of said plural proximal holes is making an angle of 5° to 20° with horizontal plane passing through long axis of medullary canal of femur to match ante version angle of head and neck of femur.

It would have been obvious to one having ordinary skill in the art to have the proximal holes make an angle of 120 degrees and 140 degrees with respect to the intramedullary canal and 5 degrees to 20 degrees with respect to the medullary canal to accommodate the different sizes of a patients. The examiner also notes that a horizontal plane can be formed anywhere through the femur, where it could be 5 degrees to 20 degrees with respect to the proximal holes.

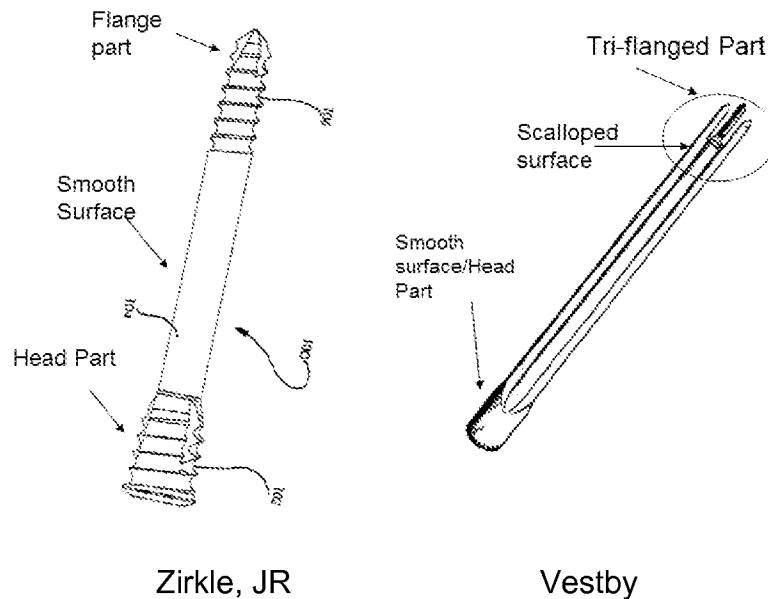
It would also have been obvious to one having ordinary skill in the art to have the proximal holes make an angle of 120 degrees and 140 degrees with respect to the intramedullary canal and 5 degrees to 20 degrees with respect to the medullary canal, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Zirkle, JR discloses the use of hip pins (#100 in Fig 10) with gliding smooth part (#104), wherein the smooth part is round and a head part (#102) but does specifically disclose that is cannulated in whole length having a triflanged part, where said triflanged part is has three flat equal surfaces (as further disclosed in claims 18-20, 24).

However, Vestby discloses a hip pin (as seen in Fig 1) is cannulated in whole length (see Col 1 lines 61-62, where the nail has a hollow body) and a triflanged part, where said triflanged part is has scalloped three flat equal surfaces (see Fig 1 below and).

It would have been obvious to one having ordinary skill in the art to modify the hip pin (#100) of Zirkle, JR with the cannulated body and triflanged part (as seen in Fig 1) of Vestby because a cannulated nail can be used with a guide wire (see col 1 lines 1619) and the triflanged part is one of many ways one of ordinary skill in the art would try to fixate a pin/nail/screw onto the bone (see Col 1 lines 65-67 in Vestby).

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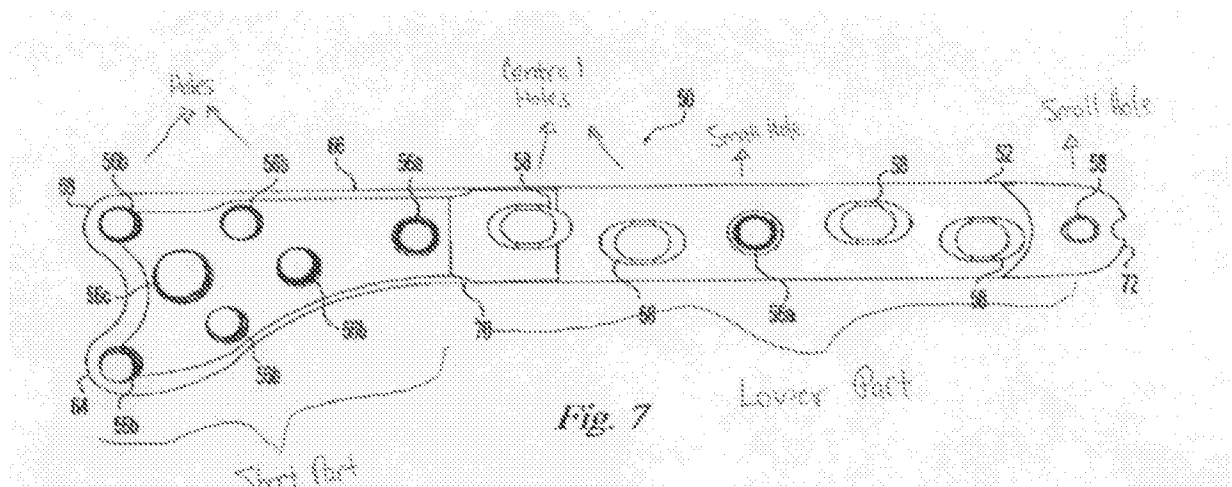
Zirkle, JR and Vestby does not specifically disclose the surfaces are up to 15-50 mm. However, it would also have been obvious to one having ordinary skill in the art to have the scalloped surfaces span from 15mm-50mm since the hip pin is to be placed within the bone, it would need to conform to the small space within the bone (see col 1 lines 65-67 in Vestby where the pin is to be used in the femur).

It would also have been obvious to one having ordinary skill in the art to have the scalloped surfaces span from 15mm-50mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

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Zirkle, JR does not also disclose a buttress plate. However it would have been obvious to one having ordinary skill in the art to use a buttress plate because plates are widely known in the art and used in dealing with bone fractures as taught by Weaver (see abstract).

Weaver discloses a buttress plate (#50 as seen in Fig 7) with holes (as seen in Fig 7 below and further recited in Claim 22). The examiner notes that any of the holes can constitute as a barrel.



However, Weaver does not specifically disclose two central large holes with at least 2mm of slit.

However, Luter discloses various bone buttress plates with slits (as seen in Figs 6, 12-14, 17-20, 27, 34).

It would have been obvious to one having ordinary skill in the art to modify two central holes (#48) of Weaver to include the slit (slots) of Luter because they help to facilitate placement of a screws and washers through the slit (as seen in Figs 26-27 and 34). It would have been obvious to one having ordinary skill in the art to have 2mm of

slit on a buttress place because the plate is to be placed in the body, wherein it would have been obvious to have 2mm of slit.

It would also have been obvious to have at least 2mm of slit, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With regard the statement of intended use and other functional statements, they do not impose any structural limitations, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Since, Zirkle, JR, Crickenberger et al, Brumfield, Vesbty, Weaver, Luter all disclose various devices used in orthopedics/bone repair, it would have been obvious to combine the references above to obtain the instant claim.

With regards to **Claim 2**, Brumfield teaches a unitary intramedullary nail of short length version (#110) is characterized having anterior curvature in said tail end to match anterior curvature of medullary canal of femur (as seen in the Fig1A and Fig 11 above) to avoid abutting of tip of said tail end to anterior cortex of middle part of shaft of femur

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and prevent stress concentration leading to pointing effect (35) with thigh pain and fracture of shaft of femur later.

With regards to **Claims 4-5**, Zirkle, JR and teaches a targeting device (as disclosed above) with a plurality of proximal holes (#26) and distal holes (#30), with the distal holes making an angle of 90 degrees (as seen in Fig 4).

Zirkle, JR does not specifically disclose the proximal holes making an angle of 120 degrees and 140 degrees with respect to the intramedullary canal and 5 degrees to 20 degrees with respect to the medullary canal.

It would have been obvious to one having ordinary skill in the art to have the proximal holes make an angle of 120 degrees and 140 degrees with respect to the intramedullary canal and 5 degrees to 20 degrees with respect to the medullary canal to accommodate the different sizes of a patients. The examiner also notes that a horizontal plane can be formed anywhere through the femur, where it could be 5 degrees to 20 degrees with respect to the proximal holes.

It would also have been obvious to one having ordinary skill in the art to have the proximal holes make an angle of 120 degrees and 140 degrees with respect to the intramedullary canal and 5 degrees to 20 degrees with respect to the medullary canal, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With regards to **Claim 6**, Zirkle, JR and teaches a targeting device (as disclosed above) with a plurality of proximal holes (#26), but does not specifically disclose having the distal holes placed in a different plane, making an angle of 5 degrees to 20 degrees with respect to the horizontal plane.

It would have been obvious to one having ordinary skill in the art to have the distal holes placed in a different plane, making an angle of 5 degrees to 20 degrees with respect to the horizontal plane to accommodate the different sizes of a patients. The examiner also notes that a horizontal plane can be formed anywhere through the femur, where it could be 5 degrees to 20 degrees with respect to the proximal holes.

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to have the distal holes placed in a different plane, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

It would also have been obvious to one having ordinary skill in the art to have the distal holes making an angle of 5 degrees to 20 degrees with respect to the horizontal plane, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to **Claims 7-8**, Zirkle, JR and teaches a targeting device (as disclosed above) with a plurality of proximal holes (#26) and distal holes (#30), wherein

the proximal holes are at a distance of "X" from the tip of the connecting end (#56) and where the distance between the holes is at a "Y" value and where the distance between the distal holes (#30) and the tip of the connecting end (#56) is at "Z" value (see Fig 1 and 4 where there is a distance between the holes and the tip of the connecting end, a distance between the proximal holes). The examiner would also like to point out that distance can always be measured in millimeters.

With regards to **Claim 9**, Brumfield teaches a unitary intramedullary nail of short length version (#110) and long length version (#10) are characterized having reducing cross section area and wall thickness of said intramedullary nail gradually from said thigh end portion to said intermediate portion or shaft to said distal knee end portion or tail to match shape of said intramedullary nail implant with shape of intramedullary canal and cortical thickness of femur to avoid high hoop stress in medullary canal while inserting said intramedullary nail (see Fig 12 above for short version and Fig 3 in Brumfield for the long version, which shows a cross-section view similar to that of Fig. 12 which shows reduced cross section and wall thickness).

With regards to **Claim 10**, Brumfield teaches a unitary intramedullary nail of short length version (#110) and long length version (#10) are characterized having axis of said knee end and said intermediate portion is concentric with axis of intramedullary canal (as seen in Figs 1-1A and see Figs above) while axis of said thigh end or head portion is making an angle.

However Brumfield does not specifically disclose the angle is of 5° to 9° with the axis of intramedullary canal and the axis of said knee end and said intermediate portion to allow entry of said intramedullary nail from tip of greater trochanter.

It would have been obvious to one having ordinary skill in the art to have the while axis of said thigh end or head portion making an angle of 5° to 9° with the axis of intramedullary canal and the axis of said knee end and said intermediate portion to match the natural curve of the bone (see Figs 1-1A).

It would also have been obvious to one having ordinary skill in the art to have the while axis of said thigh end or head portion making an angle of 5° to 9° with the axis of intramedullary canal and the axis of said knee end and said intermediate portion., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With regards to **Claims 11-12**, Zirkle, JR teaches an intramedullary nail (#12 as best seen in Figs 1 and 4), with proximal holes (#28) and distal holes (#40), with the distal holes making an angle of 90 degrees (as seen in Fig 4). Zirkle, JR does not specifically disclose the proximal holes making an angle of 120 degrees and 140 degrees with respect to the intramedullary canal and 5 degrees to 20 degrees with respect to the medullary canal. The examiner also notes that a horizontal plane can be formed anywhere through the femur, where it could be 5 degrees to 20 degrees with respect to the proximal holes.

It would have been obvious to one having ordinary skill in the art to have the proximal holes make an angle of 120 degrees and 140 degrees with respect to the intramedullary canal and 5 degrees to 20 degrees with respect to the medullary canal to accommodate the different sizes of a patients.

It would also have been obvious to one having ordinary skill in the art to have the proximal holes make an angle of 120 degrees and 140 degrees with respect to the intramedullary canal and 5 degrees to 20 degrees with respect to the medullary canal, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With regards to **Claim 13**, Zirkle, JR teaches an intramedullary nail (#12 as best seen in Figs 1 and 4), with proximal holes (#28), but does not specifically disclose having the distal holes placed in a different plane, making an angle of 5 degrees to 20 degrees with respect to the horizontal plane.

It would have been obvious to one having ordinary skill in the art to have the distal holes placed in a different plane, making an angle of 5 degrees to 20 degrees with respect to the horizontal plane to accommodate the different sizes of a patients. The examiner also notes that a horizontal plane can be formed anywhere through the femur, where it could be 5 degrees to 20 degrees with respect to the proximal holes.

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to have the distal holes placed in a different plane, since it has

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been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

It would also have been obvious to one having ordinary skill in the art to have the distal holes making an angle of 5 degrees to 20 degrees with respect to the horizontal plane, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to **Claim 14**, Zirkle, JR teaches an intramedullary nail (#12 as best seen in Figs 1 and 4), with proximal holes (#28), wherein the proximal holes are at a distance of "X1" from the tip of connecting end of the nail (#12) and where the distance between the holes is at a "Y1" value (see Fig 1 and 4 where there is a distance between the holes and the tip of the connecting end and where the distal holes are at a distance from each other). The examiner would also like to point out that distance can always be measured in millimeters.

Regarding **Claim 15**, Brumfield teaches distal holes of said short length version (#110) is characterized having distance between tip of said connecting end (see Fig above) of short length version intramedullary nail and said distal holes (#128, #130 as seen above) is kept at "ZI" value in millimeters in such a way that said distal holes of targeting device target corresponding said distal locking holes of said short length version intramedullary nail before anterior curvature of femur starts to get sure distal

interlocking of said nail with femur without any chance to miss the said distal holes in said nail (see Figs above, where there is a distance between the connecting and the distal holes, where the examiner notes that distance can always be measured in millimeters).

With regard to **Claim 16**, Zirkle, JR teaches an intramedullary nail (#12 as best seen in Figs 1 and 4), where the proximal holes are round (see paragraph 32, where the #28 maybe have a circular cross section or non-circular geometry), which is capable of receiving a sliding pin, which is congruently shaped to the proximal hole.

With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims, which is capable of being used as claimed if one so desires to do so. In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

With regard to **Claim 17**, Zirkle, JR teaches an intramedullary nail, where the there is a relatively smaller diameter of the thigh end (as seen in Fig 4).

With regard to **Claim 25**, Zirkle, JR and Vestby teaches thigh end part or head of said intramedullary nail, said proximal holes in intramedullary nail and said proximal hip

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pins are characterized having smaller diameter (since the intramedullary nail and hip pins are to be used in bone, it is obvious that their diameter would be small to accommodate the size of the bone).

With regards to **Claim 26**, Zirkle, JR, Crickenberger et al, Brumfield, Vesbty, Weaver, and Luther teach short length version intramedullary nail and long length version intramedullary nail and said proximal sliding hip pins, said barrels said buttress plate, said interlocking screws are made of stainless steel or titanium or other bio compatible material (since all devices taught by Zirkle, JR, Crickenberger et al, Brumfield, Vesbty, Weaver, and Luther are all used for within the body they would obviously be made out of bio compatible material).

11. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Zirkle, JR US 2002/0151897, Crickenberger et al US 5,728,128, Brumfield US 5,562,666, Vesbty US 3,892,233, Weaver US 6,623,486, and Luter US 5,951,557 as applied to claim 1 above, and further in view of Middleton US 2003/0083662.

The combination above discloses the claimed invention as stated above but does specifically disclose the triflanged part having multiple holes of at least 2mm connecting with the central cannulation.

However Middleton discloses a bone pin (#130 as seen in Fig 1A) with a central cannulation (#132) with multiple holes (#134), but does not disclose the holes being at least 2mm.

It would have been obvious to one having ordinary skill in the art to modify the hip pin of Zirkle, JR and Vestby to include the holes (#134) of Middleton because the holes (#134) are adapted for the flow of in-situ hardenable material (see paragraph 34), wherein the material is bone cement (see paragraph 37). It would also have been obvious to one having ordinary skill in the art to have holes of at least 2mm due to the small space within the body to sufficiently supply material through the holes.

It would also have been obvious to one having ordinary skill in the to have holes of at least 2mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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